Remarks

The Applicants confirm the earlier election of Claims 1-9 and withdrawal of Claims 10-15. The Applicants respectfully request that further treatment of Claims 10-15 be held in abeyance pending allowance of Claims 1-9. The Applicants nonetheless stand ready to cancel Claims 10-15 upon allowance of Claims 1-9 without prejudice and without disclaimer of the subject matter therein. Moreover, the Applicants would specifically reserve the right to file one or more divisional applications directed to such subject matter.

Claim 9 stands rejected under 35 U.S.C. §112 as being indefinite. The Applicants note with appreciation the Examiner's helpful reference to the abbreviation "DSC." The Applicants respectfully submit that those skilled in the art easily know that DSC stands for Differential Scanning Calorimetry. Moreover, the full designation of this phrase is set forth in the Specification such as on page 3, at line 19 in conjunction with the abbreviation. The Applicants respectfully submit that one skilled in the art can easily consult the Applicants' Specification in interpreting the meaning of the phrase and easily determine that definition. Thus, the Applicants respectfully submit that Claim 19 is already in accordance with §112, second paragraph. The Applicants have nonetheless amended Claim 9 to insert "Differential Scanning Calorimetry" to facilitate allowance. Withdrawal of the rejection is respectfully requested.

Claims 1-9 are provisionally rejected on the grounds of nonstatutory obviousness-type double-patenting over Claims 38-42 of co-pending Application No. 10/143,111, Claims 1-21 of co-pending Application No. 11/447,560 and Claims 1-9 of co-pending Application No. 11/447,714. The Applicants note that inasmuch as this rejection is "provisional," further treatment of that rejection is not necessary at this time. The Applicants accordingly respectfully request that this rejection be held in abeyance pending allowance of at least one of the other co-

pending applications.

Claim 1 is also rejected on the ground of non-statutory obviousness type double patenting over Claim 1 of US Patent 6,168,805 (US '805). The Applicants note with appreciation the Examiner's helpful comments hypothetically applying Claim 1 of the US '805 patent against Claim 1 of this Application. The Applicants nonetheless respectfully submit that Claim 1 of US '805 does not render Claim 1 of this Application obvious. Reasons are set forth below.

The Applicants first reproduce Claim 1 below for the Examiner's convenience as follows:

> 1. A process of preparing a controlled release oral dosage form comprising:
> (a) missing an active pharmaceutical ingredient and an acrylic polymer to yield a mixture;
> (b) forming said mixture into a solid unit dosage form, and
> (c) curing said solid unit dosage form

The Applicants similarly reproduce Claim 1 of US '805 below for the Examiner's convenience as follows:

> 1. A process for preparing solid, amorphous paroxetine comprising:
> (a) mixing paroxetine free base or a pharmaceutically acceptable paroxetine salt with water and pharmaceutically acceptable polymer; and
> (b) drying to form a composition comprising solid amorphous paroxetine and polymer wherein said polymer is at least partially water soluable.

The Applicants respectfully submit that there are significant differences between these two processes. That is because the processes are very different from one another. Claim 1 of US '805 has a mixing step of paroxetine free base with water and a polymer followed by a drying step. This is sharply contrasted to Claim 1 that recites mixing an active agent with an acrylic polymer, forming the mixture into a solid unit dosage form and then curing that solid unit dosage form. The Applicants respectfully submit that not only are these processes different, but the process of Claim 1 of US '805 does not render the Claim 1 of this Application obvious.

The reasons are surprisingly straightforward inasmuch as Claim 1 of US '805 does not recite the formation of a solid unit dosage form. Instead, Claim 1 of US '805 dries a mixture to form a composition. There is no explicitly recited step of forming the solid usage dosage form in Claim 1. (Of course, there could be a further step in US '805 of forming a solid unit dosage form subsequent to the drying step which forms a composition.) This is sharply contrasted to Claim 1 of this Application which takes the mixture and forms a solid unit dosage form. Then, subsequent to forming the solid unit dosage form, the solid unit dosage form is cured. Thus, we have a situation where Claim 1 of US '805 does not form a solid unit dosage form while Claim 1 of this Application affirmatively claims forming a solid unit dosage form. This results in an inability to cure a solid unit dosage form in the case of Claim 1 of US '805 because a solid unit dosage form was never manufactured.

In the case of Claim 1 of US '805, forming the solid unit dosage form would occur subsequent to the drying step. In sharp contrast, the Applicants do just the opposite in their Claim 1 wherein curing is performed after formation of the solid unit dosage form. The fact that the Applicants' Claim 1 does essentially the opposite of what would theoretically be done to the dried composition of Claim 1 of US '805 stands in support of the separate patentability of Claim 1 of this Application because it is well known that doing essentially the opposite of what the prior art teaches is compelling evidence of nonobviousness. Thus, the Applicants respectfully submit that Claim 1 of this Application is not obvious over the very different process in the very different claimed steps of Claim 1 of US '805. Withdrawal of the double-patenting rejection is respectfully requested.

The Applicants also respectfully submit that reading Claim 1 of US '805 in the context of its accompanying disclosure confirms the very different and opposite teachings of US '805.

Reference to the numerous examples in US '805 helps confirm those differences. For example, Example 1 recites a formation of a wet mixture which is subsequently dried in a tray oven at 60° C for 71 hours. The result is an amorphous form of paroxetine hydrochloride. No tablets are formed and no curing of the tablets is disclosed. Examples 2-5 take a different approach and form a web mixture that is dried under static vacuum or spray dried. A powder is formed, yet there is no formation of the tablet and no curing of the tablet.

Examples 6 and 7 take yet another approach wherein a tablet is formed. In those instances, the solid dispersions formed in Examples 3 and 4, respectively, are milled and then compressed into tablets. Those tablets are then coated with a film coating. There is no curing of the compressed tablets either before or after coating. Thus, the Applicants respectfully submit that the teachings in the US '805 Specification confirm that Claim 1 of US '805 does not render this Claim 1 obvious. Withdrawal of the rejection is again respectively requested.

Claims 1-8 stand rejected under 35 U.S.C. §102 as being anticipated by Oshlack. The Applicants note with appreciation the Examiner's helpful comments hypothetically applying Oshlack against those rejected claims. The Applicants nonetheless respectfully submit that Oshlack fails to explicitly or implicitly disclose all of the subject matter of Claims 1-8. Reasons are set forth below.

Oshlack discloses controlled release oxycodone compositions made from processes that are completely different from the processes recited in Claims 1-8. The general process disclosed by Oshlack may be found in the upper portion of Column 5 wherein granules are formed, the granules are mixed with an alcohol and then the resulting mixture is optionally compressed and shaped. However, Oshlack additionally discloses a drying step. This may be found in Example 1 as noted in the rejection wherein oxycodone hydrochloride, spray-dried lactose and Eudragit

are mixed together and then granulated with water to produce a moist granular mixture. The granules are then dried in a fluid bed dryer at 60° C, screened, redried and rescreened. This is followed by addition of melted stearyl alcohol. The coated granules are then allowed to cool, followed by screening. The screen material is then mixed with talc and magnesium stearate and that resulting mixture is compressed into tablets.

Thus, a process is disclosed wherein wet granules are dried and then the dried granules are compressed. This is sharply contrasted to Claim 1 which specifically recites mixing and forming a resulting mixture into a solid unit dosage form followed by curing. These are completely different processes. In that regard, it must be remembered that §102 requires that the subject matter of Claims 1-8 is explicitly or implicitly disclosed in its entirety by Oshlack. The Applicants respectfully submit that the Oshlack disclosure is explicitly different from the Applicants' claimed subject matter as recited in Claims 1-8. That is because Oshlack mixes, dries and then forms tablets. The Applicants do not do this in Claims 1-8. Instead, they take a virtually opposite approach where they mix, form a solid unit dosage form and then cure the resulting solid unit dosage form.

The Applicants provide two side-by side Tables below that abbreviate the subject matter of Claim 1 versus the steps of Example 1 in Oshlack. The Table of the Applicants' Claim 1 contains the steps of mixing, forming a solid unit dosage form and curing the solid unit dosage form. Those three steps are directly placed beside the corresponding steps in Oshlack wherein there is disclosed mixing, drying and forming tablets.

Claim 1	**Oshlack Example 1**
Mix	Mix
Form solid unit dosage form	Dry
Cure	Form Tablet

It can be seen that there are corresponding mixing steps on the first line. However, after the first

line, the disclosure of Oshlack diverges dramatically from Claim 1. Oshlack dries the mixture. The Applicants' Claim 1 does not dry the mixture. Instead, the Applicants' Claim 1 forms the solid unit dosage form. Then, the third step of Oshlack is forming a tablet. Again, the Applicants do not do this. Instead, the Applicants cure the already formed solid unit dosage form. The Applicants respectfully submit that the disclosure of Oshlack is explicitly different from the subject matter of Claim 1 as opposed to being explicitly (or implicitly) the same as the Applicants' Claim 1. Accordingly, the Applicants respectfully submit that Oshlack is inapplicable.

Although the above Tables referred to Example 1 of Oshlack, that Table does not deviate substantially from the other examples. For example, Example 2 also uses a fluid bed drier subsequent to mixing and before compressing granules. Example 3, on the other hand, does not specify drawing but only refers to a "dry granulation" prior to compression. Thus, the Applicants respectfully submit that the essence of Oshlack is reproduced in the Table above with respect to Oshlack Example 1 and that there is no other disclosure that explicitly or implicitly matches the Applicants steps as recited in Claim 1. Withdrawal of the rejection of Claims 1-8 based on Oshlack is respectfully requested.

In light of the foregoing, the Applicants respectfully submit that the entire Application is now in condition for allowance which is respectfully requested.

Respectfully submitted,

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